UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

JOSHUA DAVID FRISKE, Individually and as Personal Representative of the Estate of Kathryn Friske, ET AL., Plaintiffs,	§	**Case no. 3:11-cv-00130-F**
v.	§	
ALZA CORPORATION and SANDOZ, INC., Defendants.	§	

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR PARTIAL DISMISSAL AND GRANTING PLAINTIFFS' MOTION FOR LEAVE TO AMEND

BEFORE THE COURT is a Motion for Partial Dismissal filed by Defendants ALZA Corporation and Sandoz, Inc. on February 25, 2011 (Docket No. 8). Plaintiffs filed a Response on March 18, 2011 (Docket No. 11). Defendants filed a Reply on April 1, 2011 (Docket No. 13). The Court held a hearing regarding this Motion on April 26, 2011. After considering the arguments of the parties, it is the opinion of the Court that Defendants' Motion for Partial Dismissal should be GRANTED IN PART AND DENIED IN PART.[1] Furthermore, the Court is of the opinion that Plaintiffs' Motion for Leave to Amend their Complaint, contained within their Response, should be GRANTED.

[1]This resolves Docket No. 8.

I. Factual and Procedural Background

In reviewing a Rule 12(b)(6) motion to dismiss, a court must accept all well-pleaded facts as true and view them in the light most favorable to the plaintiff. *Sonnier v. State Farm Mut. Auto. Ins. Co.*, 509 F.3d 673, 675 (5th Cir. 2007); *Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004).

Kathryn Friske ("Friske") suffered from fibromyalgia, which caused pain in her muscles, tendons, and ligaments, and osteoarthritis, which caused pain and stiffness in her joints. As part of her treatment to control the pain, Friske's doctor, Pamela Banister, prescribed transdermal Fentanyl patches. These patches contain an analgesic, and deliver a specific dose of medication into the blood stream through the skin for the purpose of pain relief. Dr. Banister prescribed patches to Friske that would deliver Fentanyl into her blood stream at rates of 25 micrograms per hour or 100 micrograms per hour. Defendants designed, manufactured, and distributed these patches, which contained a "reservoir" of the Fentanyl gel within two layers of the patch.

Friske's last prescription for Fentanyl patches was filled on January 20, 2009. Friske was wearing one of her prescribed patches on January 22, 2009, when she died at the age of 49. Plaintiffs, her survivors, allege that her death was caused by excessive amounts of Fentanyl in her blood, which was present due to defective Fentanyl patches manufactured and sold to Plaintiff by Defendants. Plaintiffs claim that the Fentanyl patch was manufactured defectively and created an unreasonable risk of a Fentanyl overdose. Plaintiffs also allege that a safer "sealed multi-laminate" and "matrix" design existed at

the time the patches at issue were produced, and that such a design was not utilized by Defendants. Plaintiffs also claim that Defendants did not reveal the dangers of their patch's design to the Food and Drug Administration ("FDA"), and that the FDA did not therefore have an opportunity to approve of the product's labeling with knowledge of the full dangers of the product. Plaintiffs assert that Defendant's labeling failed to warn of the risks and dangers allegedly associated with the use of the patch, making the product unreasonably dangerous. Plaintiffs further note that on February 12, 2008, Defendant recalled certain 25 mcg/hour Fentanyl patches, which were to expire in December 2009, because of a cut along one side of the drug reservoir within the patch. Friske was wearing a 25 mcg/hour Fentanyl patch at the time of her death. Plaintiffs also note another recall of such patches that took place in 2004.

Plaintiffs filed this action on January 19, 2011, raising several claims against Defendants. In their Motion, Defendants seek dismissal of Plaintiffs' claims for marketing defect, design defect, negligence, negligent misrepresentation, and breach of implied warranty of fitness.[2]

II. Rule 12(b)(6) Motion to Dismiss Standard

A motion to dismiss under Rule 12(b)(6) should be granted only if the complaint does not include "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference

[2]The instant Motion does not seek dismissal of certain of Plaintiffs' other claims.

that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, ___ U.S. ___, ___, 129 S. Ct. 1937, 1949 (2009). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556). However, a complaint will not overcome a Rule 12(b)(6) motion "if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*

III. Discussion

Defendants seek dismissal of Plaintiffs' claims for marketing defect, negligent misrepresentation, design defect, breach of implied warranty of fitness, and negligence. The Court shall address each of these claims in turn.

A. Marketing Defect

A marketing defect occurs when a defendant knows or should know of a potential risk of harm but markets it without adequately warning of the danger or providing instructions for safe use. *Wright v. Ford Motor Co.*, 580 F.3d 263, 274 (5th Cir. 2007); *Sims v. Washex Machinery Corp.*, 932 S.W.2d 559, 562 (Tex. App.–Houston [1st Dist.] 1995, no writ). Plaintiffs must demonstrate the following elements to maintain their marketing defect claim: (1) a risk of harm inherent in the product or which may arise from the intended or reasonably anticipated use of the product; (2) the product supplier actually knew or should have reasonably foreseen the risk of harm at the time the product

was marketed; (2) the product contains a marketing defect; (4) the absence of a warning renders the product unreasonably dangerous to the ultimate user or consumer of the product; and (5) the failure to warn must constitute a causative nexus in the product user's injury. *Wright*, 508 F.3d at 274-75.

Defendants argue that Plaintiffs' marketing defect claim should be dismissed for two reasons. First, Defendants allege that Texas law creates a presumption that FDA-approved warnings are adequate, and that Plaintiffs cannot rebut this presumption because the relevant exception is preempted by federal law. Second, Defendants assert that Plaintiffs have failed to state sufficient facts to plead the fraud-on-the-FDA exception to the presumption at issue under Federal Rule of Civil Procedure 12(b)(6). The Court shall address each of these arguments in turn.

1. Preemption

The first question that the Court must address is whether, in this case, federal law preempts Plaintiffs' ability to assert the fraud-on-the-FDA exception to the presumption that Defendants are not liable for claims of marketing defect because their labels were approved by the FDA. It is well-established that "the Supremacy Clause, U.S. Const., Art. VI, cl. 2, invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-13 (1985) (quoting *Gibbons v. Ogden*, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824)). While Congress can expressly preempt state law within the language of a federal statute, *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977), state law can also be impliedly preempted by the

existence of comprehensive federal law that leaves no room for state regulation, a federal interest so dominant that it precludes the enforcement of state laws on the subject, or when the federal and state law is conflicted to the extent that the two cannot be executed alongside each other or where the state law unacceptably obstructs the full purposes and objections of Congress. *See Castro v. Collecto, Inc.*, 634 F.3d 779, 785 (5th Cir. 2011) (citations omitted). However, "because the States are independent sovereigns in our federal system, [the Supreme Court] ha[s] long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

The preemption issue in this case goes not to Plaintiffs' actual claim for marketing defect, but whether Plaintiffs' may rebut a presumption that involves a provision referencing federal law. Defendants assert that they are entitled to a presumption that their warnings were adequate under Texas law. Specifically, Section 82.007 of the Texas Civil Practice and Remedies Code provides:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> > (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration . . . .

Texas law therefore presumes that FDA-approved labels are adequate. *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 774 (S.D. Tex. 2008) (Tagle, J.). However, "[t]he claimant may rebut th[is] presumption . . . as to each defendant by establishing that . . . the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." TEX. CIV. PRAC. & REM. CODE § 82.007(b).[3]

There is no dispute that the warning labels at issue were approved by the FDA; therefore, Defendants are entitled to the presumption that their labels are adequate. Plaintiffs assert that this presumption is rebuttable by asserting the fraud-on-the-FDA exception provided in Section 82.007(b). Plaintiffs argue that their Complaint successfully invokes the fraud-on-the-FDA exception to the presumption of validity.

Defendants argue that the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), acts to preempt the fraud-on-the-FDA exception to the presumption. In *Buckman*, a number of patients sued the manufacturer of orthopedic bone screws inserted into their spines, alleging that the manufacturer's regulatory consultant made fraudulent representations to the FDA. *Id.* at 343. The patients sued the manufacturer under a Michigan law that permitted consumers to raise stand-alone claims against manufacturers for perpetrating fraud upon the FDA. *Id.* at

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[3]This provision provides several other exceptions, but Plaintiff only asserts the "fraud-on-the-FDA" exception.

346-47. The Supreme Court held that the state law fraud-on-the-FDA claims conflicted with federal law, and therefore were impliedly preempted. *Id.* at 348. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* The Court cited the detailed statutory scheme already in place, the evaluation methods and enforcement mechanisms already in place under federal law, and the burden that allowing such claims would place upon the FDA by provoking applicants for approval of labels "to submit a deluge of information that the [FDA] neither wants nor needs." *Id.* at 348-51. The Court also noted that "[p]olicing fraud against federal agencies is 'hardly a field which the States have traditionally occupied.'" *Id.* at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Furthermore, the state law claims at issue "exist[ed] solely by virtue of the [federal law] disclosure requirements." *Id.* at 353. The Supreme Court therefore determined that the state law fraud-on-the-FDA claims were preempted by this preexisting federal statutory scheme.

Defendants argue that *Buckman* governs in this case, and that Section 82.007(b)'s fraud-on-the-FDA exception to the presumption is preempted. However, the situation before the Court does not involve state law claims for fraud-on-the-FDA; instead, it involves the rebutting of a presumption if such behavior is demonstrated. The Court must determine whether *Buckman* should be extended to apply to this situation, in which

Defendants argue that a provision establishing an exception to a presumption, rather than a stand-alone claim, should be preempted.

Federal courts have split on the question of whether *Buckman* should be extended to fraud-on-the-FDA exceptions. Some courts have held that *Buckman*'s reasoning applies equally to fraud-on-the-FDA claims and exceptions. For example, in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), the Sixth Circuit found the distinction between fraud-on-the-FDA claims and exceptions "immaterial," affirming a district court's determination that "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Id.* at 965-66. The *Garcia* court determined that the fact that the law at issue did not create "a specific cause of action for fraud on the FDA" but instead created an exception to a provision establishing a presumption of liability did not distinguish the situation from *Buckman*, and that the exception was therefore preempted. *Id.* at 966.

By contrast, the Second Circuit reached the opposite conclusion in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006).[4] The *Desiano* court looked to the purposes of the statutory scheme, and concluded that the "fraud-on-the-FDA" exception was not intended to "[p]olice fraud against federal agencies," *Buckman*, 531 U.S. at 347, but instead "f[e]ll[] squarely within [the state's] prerogative to 'regulat[e] matters of health and safety.'" *Desiano*, 467 F.3d at 94 (quoting *Buckman*, 531 U.S. at 348, and *Medtronic*, 518 U.S. at 485). Looking at the purpose of the statute and its legislative

[4]Interestingly, both of these cases were interpreting the same Michigan law.

history, the *Desiano* court determined that the goal of the provision was not to police fraud against a federal agency and interfere with the federal government's regulatory prerogative. *Id.* Instead, "[t]he object of the legislative scheme was rather to regulate and restrict when victims could continue to recover under preexisting state products liability law." *Id.*

The *Desiano* court proceeded to distinguish the fraud-on-the-FDA exception to the fraud-on-the-FDA cause of action in *Buckman* by noting that the underlying cause of action stemmed from traditional state law claims and duties. *See id.* at 94-95 ("None of [the claims] derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency."). Unlike in *Buckman*, in which liability could be established by proving fraud on the FDA, the claims in *Desiano* were "not premised principally (let alone exclusively) on a drug maker's failure to comply with federal disclosure requirements." *Id.* at 95. Therefore, as the claims at issue in *Desiano* were not "based *solely* on the wrong of defrauding the FDA," *id.*, the Second Circuit determined that, absent specific congressional action, a fraud-on-the-FDA exception to immunity, rather than a cause of action itself, was not preempted. The *Desiano* court ultimately determined,

> Finding preemption of traditional common law claims where fraud is not even a required element–but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law–would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of

> fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and MDA as having that effect.

Id. at 96.[5]

District courts within this Circuit have also split on the issue. In *Ackerman v. Wyeth Pharmaceuticals*, 471 F. Supp. 2d 739 (E.D. Tex. 2006), Judge Schneider declined to hold that fraud-on-the-FDA exception was preempted because it does not "create a cause of action" and evidence introduced to rebut the presumption "does not establish liability." *Id* at 749. Similarly, in *Pustejovsky v. Wyeth, Inc.*, 4:07-cv-103-Y, Order Denying Mot. for Summ. J. and Mot. to Strike (N.D. Tex. Nov. 29, 2007), Judge Means held that "because section 82.007 . . . merely creates a presumption that [the defendant] may rely upon in its defense" rather than "creat[ing] a cause of action for fraud on the FDA," *id.* at 2-3, plaintiffs were given the opportunity to utilize the exception to rebut the presumption of adequate labeling. *Id.* at 3 ("Because discovery is not completed in this case, it would be inappropriate at this time to state that Plaintiff has not rebutted [the defendant's] statutory presumption.").

By contrast, in *Lofton v. McNeil Consumer & Speciality Pharmaceuticals*, 682 F.2d 662 (N.D. Tex. 2010), Judge Lindsay adopted the rationale of *Garcia* and

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[5]The *Desiano* decision was affirmed by an equally divided Supreme Court with no opinion. *Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440, 441 (2008). The Supreme Court's affirmance of *Desiano* is therefore not binding upon this Court. *See Hertz v. Woodman*, 218 U.S. 205, 213-14 (1910) ("[A]n affirmance by an equally divided court is, as between the parties, a conclusive determination and adjudication of the matter adjudged; but the principles of law not having been agreed upon by a majority of the court sitting prevents the case from becoming an authority for the determination of other cases, either in this or inferior courts.").

extended *Buckman* to preempt the fraud-on-the-FDA exception to the presumption, determining that "the concerns in *Buckman* hold true not only where a plaintiff brings a fraud-on-the-FDA but also where it seeks to show an exception to the presumption here." *Id.* at 675. Judge Means therefore held, "To avoid any intrusion upon the FDA's right to police fraud itself, the court follows *Garcia* and finds that section 82.007(b)(1) is preempted in some circumstances, including as here, where Plaintiffs ask the court to reach the conclusion opposite of that reached by the FDA, that Defendants did not withhold information or mislead it." *Id.*[6]

After considering both approaches, the Court is of the opinion that the fraud-on-the-FDA exception is not preempted under *Buckman*, and shall follow the reasoning in *Desiano* and like-minded cases. Unlike the claim in *Buckman*, the claim in this case does not arise solely due to federal law; instead, it is an exception to a presumption that provides immunity from liability to a claim that arises solely under Texas state law. *Buckman* specifically distinguished the claims in that case, which were based entirely upon violations of federally-imposed regulations, to claims that were based upon state

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[6]District courts outside of this circuit are also split on the issue of whether *Buckman* extends beyond stand-alone fraud-on-the-FDA claims to fraud-on-the-FDA exceptions to presumptions. *See, e.g., In re Medtronic, Inc.*, 465 F. Supp. 2d 886, 899-900 (D. Minn. 2006) (declining to hold that "*Buckman* forecloses any inquiry into the FDA regulatory process" and that "plaintiffs may use evidence–if they are able to produce it–of Medtronic's efforts to manipulate the regulatory process in order to prove their negligence and strict liability claims, but they may not bring an independent claim for relief based on fraud-on-the-FDA"); *contra, e.g., In re Aredia & Zometa Prods. Liability Litig.*, Nos. 3:06-MD-1760 *et al*, 2008 WL 2944910, at *4-*5 (M.D. Tenn. July 25, 2008) (holding that "the federalism concerns of *Buckman* and *Garcia* are still present" in fraud-on-the-FDA exceptions as well as claims, and holding a fraud-on-the-FDA exception to be preempted).

duties and underlying claims. The Supreme Court noted that the claims in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), were "not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant." *Buckman*, 531 U.S. at 352 (citing *Silkwood*, 464 U.S. at 241). Furthermore, in *Silkwood*, there was an express Congressional intent within the relevant statute to disclaim any interest in fashioning the tort remedies laid out in state law. *Id.* (citing *Silkwood*, 464 U.S. at 257). The Supreme Court also distinguished *Medtronic*, noting that the claims in that case "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." *Id.* (citing *Medtronic*, 518 U.S. at 481). Accordingly, the Supreme Court cabined its holding in *Buckman* preempting state law claims to a situation where the cause of action "exist[ed] solely by virtue" of the requirements of the FDCA rather than claims that were based upon traditional state tort duties and claims. *Id.* at 353.

The Fifth Circuit recently provided support for this position in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011). In holding that a negligence claim was not analogous to the fraud-on-the-FDA claim held preempted by *Buckman*, the *Hughes* court wrote,

> The plaintiffs in *Buckman* were attempting to assert a freestanding federal cause of action based on violation of the FDA's regulations; the plaintiffs did not assert violation of a state tort duty. In contrast, Hughes is asserting a Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of product. She seeks to prove Boston Scientific's breach

> of the state duty by showing that Boston Scientific violated the FDA's MDR regulations. Because Hughes is asserting a recognized state tort claim, her claim is comparable to the tort claims in *Silkwood* and [*Medtronic*] that *Buckman* recognized as surviving implied preemption.

Id. at 775. The Fifth Circuit accordingly recognized that claims based upon an underlying state duty and tort claim were not preempted, despite the plaintiff's need to demonstrate a violation of federal regulations. As the claims in this case are based upon recognized state duties and tort claims, it appears that *Hughes* supports the notion that these claims are not preempted.

The Court is therefore of the opinion that the fraud-on-the-FDA exception is not preempted by federal law because the claim asserted by Plaintiffs themselves is based upon violations of traditional state law duties rather than federally imposed law or regulations. In support of this decision, the Court notes that in *Desiano*, the Second Circuit addressed the Sixth Circuit's reasoning in *Garcia*, writing, "[U]nder *Garcia*'s reading of *Buckman*, unless a state barred the admission of evidence of fraud against the FDA in run of the mill tort cases, the policy concerns expressed in *Buckman* would seemingly justify invalidating any product liability suit brought against a drugmaker. We do not believe *Buckman* meant to go anywhere near so far." *Desiano*, 467 F.3d at 97.

The Court agrees with the Second Circuit's analysis. *Buckman*'s holding invalidated claims for individual recovery based upon fraud that manufacturers perpetuated upon the FDA. If the Court were to accept Defendant's argument, then the holding of *Buckman* would be extended to impact claims that are based entirely on state

law. The impact of the fraud-on-the-FDA provision only comes into play in rebutting a presumption of adequacy, and the Court does not read *Buckman* to bar Plaintiffs from introducing evidence that would counter this presumption under Texas law. The Court is hesitant to apply the doctrine of preemption to essentially bar a claim that did not arise "solely by virtue" of federal law. *Buckman*, 531 U.S. at 353. Unlike in *Buckman*, the nature of Defendants' alleged liability in this case does not arise from its statements to a federal agency; while those actions are relevant to the Court's analysis, that behavior provides no independent basis for Plaintiffs to obtain a recovery. Instead, evidence of that behavior only acts to counter a statutory presumption asserted by Defendants.

Furthermore, the law in this case pertains to an area in which the state possesses an especially strong interest and regulatory prerogative: providing for the health and safety of its citizens. *Medtronic*, 518 U.S. at 485; *see also Wyeth v. Levine*, 129 S. Ct. 1187, 1195 n.3 (2009) (noting that a presumption against preemption applies to matters of "state regulation of health safety"). Much like the law at issue in *Garcia* and *Desiano*, "[t]he object of the legislative scheme was . . . to regulate and restrict when victims could continue to recover under preexisting state products liability law." *Desiano*, 467 F.3d at 94. There is no indication that Section 82.007(b)(1) intended to or will interfere with the FDA's ability and prerogative to police fraud perpetrated upon itself. Instead, this provision is merely establishes a presumption that can be rebutted by the introduction of evidence indicating that Defendants committed the behavior outlined in the exception.

The Court is mindful of the concerns expressed in *Buckman* that permitting claims based on fraud-on-the-FDA would create an unwanted burden upon the federal agency and would counsel in favor of preemption. *Buckman*, 531 U.S. at 351; *see also Hughes*, 631 F.3d at 775 ("Notably, Hughes's claim does not depend on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue, as in *Buckman*."). However, the Court is persuaded by the Second Circuit's reasoning in *Desiano*:

> In terms of deluging the FDA, there is little difference between (a) causes of action, like the instant one, where proof of fraud against the FDA is not the basis of the cause of action but is necessary to negate a limitation on state liability, and (b) causes of action where proof of fraud against the FDA is permitted but not conclusive . . . . So long as a court or jury is *allowed to consider* evidence of fraud against the FDA in an ordinary common law tort suit, and so long as juries are likely to react to such evidence, there will be substantial inducements on the pharmaceutical industry to provide the federal agency with just the kind of information that troubled the *Buckman* and *Garcia* Courts. Requiring such evidence when a plaintiff seeks to counter a statutory defense from liability would not significantly alter that incentive. Only when proof of fraud is by itself *sufficient* to impose liability–and indeed is the sole basis of liability (as it was in *Buckman*) –does the incentive to flood the FDA appreciably escalate.

Desiano, 467 F.3d at 97 (emphasis in original). As the evidence presented under the provision at issue would not impose liability upon defendants, the likelihood that the FDA will be presented with a deluge of unwanted requests and tasks is diminished.[7]

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[7]While Judge Lindsay adopted the reasoning of *Garcia* and held that the exception at issue here raised the same concerns as fraud-on-the-FDA claims themselves, the Court observes that Judge Lindsay noted that Section 82.007(b)(1) "is preempted *in some circumstances*, including as here, *where Plaintiffs ask the court to reach the conclusion opposite that of the FDA, that Defendants did not withhold information or mislead it.*" *Lofton*, 682 F. Supp. 2d at 675 (emphasis added). In this case, there has been no presentation

Ultimately, the Court agrees with *Desiano* and other like-minded district courts that have declined to extend *Buckman* beyond claims that solely seek recovery based upon fraud against a federal agency when a statutory scheme for such relief already remains in place. As the law at issue in this case specifically involves "the historic primacy of state regulation in matters of health and safety," *Medtronic*, 518 U.S. at 485, and the claims themselves arise from traditional state tort duties and claims, the Court is of the opinion that, without the explicit guidance of federal law, the state law exclusion at issue is not impliedly preempted.

2. Sufficient Factual Allegations

Although the Court has determined the fraud-on-the-FDA exception in Section 82.007(b)(1) is not preempted by federal law, the Court still must resolve issues surrounding Plaintiffs' pleadings in regard to that presumption. Defendants argue that even if Section 82.007(b)(1) is not preempted, Plaintiffs have failed to provide sufficient factual allegations to assert the relevant exception under the pleading standards established in *Twombly* and *Iqbal*. Plaintiffs argue that they only need to state enough facts to demonstrate that they are entitled to relief, and that the pleading standards of *Twombly* and *Iqbal* should not be applied to pleading exceptions to presumptions.

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of such a finding by the FDA at this early stage; accordingly, the situation in this case differs from that seen in *Lofton*. Furthermore, despite the fact that Judge Lindsay chose to follow *Garcia* rather than *Desiano*, because the particular circumstances seen in *Lofton* are absent, this decision is not inconsistent with Judge Lindsay's ultimate decision in *Lofton*.

The *Twombly* and *Iqbal* decisions have fermented significant changes and developments in federal litigation, and many issues arising from these decisions remain to be resolved. While it was established even before *Twombly* and *Iqbal* that "[a]n affirmative defense is subject to the same pleading requirements as is the complaint," *Woodfield v. Bowman*, 193 F.3d 354, 362 (5th Cir. 1999), among the issues still in dispute is whether the pleading standards laid out in those case apply to the pleading of exceptions to presumptions.

The Court is of the opinion that the pleading standards apply to presumptions and exceptions to presumptions as well as the pleadings of claims and affirmative defenses. In *Twombly*, the Supreme Court noted that plaintiffs faced with a Rule 12(b)(6) motion must provide sufficient factual allegations establishing the grounds for "*entitlement to relief*." *Twombly*, 550 U.S. at 555 (emphasis added). The Court reads this as requiring factual allegations that demonstrate that the plaintiff is entitled to relief, which would include pleading facts that would rebut a presumption asserted by Defendant. *See In re Dell, Inc. ERISA Litig.*, 563 F. Supp. 2d 681, 693 (W.D. Tex. 2008) (Sparks, J.) (after noting that a plaintiff must plead all of the essential elements of his or her claim, holding that "[t]he Court must therefore determine *at the motion to dismiss stage* whether the Plaintiffs have plead facts which, taken as true, could overcome [a] presumption") (emphasis added); *Halaris v. Viacom, Inc.*, 3:06-CV-1646-N, 2007 WL 4145405, at *9 (N.D. Tex. Sep. 21, 2007) (Godbey, J.) (in ERISA case, requiring pleading of facts to

overcome presumption); *see also Johnson v. Odom*, 910 F.2d 1273, 1277 (5th Cir. 1990) (noting that a party "pleaded facts sufficient to overcome a presumption of immunity").

The need for specific pleadings is especially important in regard to the exception asserted here, which involves proof of fraud perpetuated on the FDA, because the Federal Rules of Civil Procedure establish a different pleading standard for fraud. "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b).[8] This heightened pleading standard existed long before the *Twombly* and *Iqbal* decisions, and has been recognized as requiring more specificity than other type of pleadings. The Fifth Circuit has "stated that Rule 9(b) requires that the plaintiff allege the particulars of time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what that person obtained thereby, otherwise referred to as the who, what, where, when, and how of the alleged fraud." *United States ex rel. Willard v. Humana Health Plan of Texas, Inc.*, 336 F.3d 375, 384 (5th Cir. 2003) (citations and internal quotation marks omitted); *see also Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005) (noting that "the Rule 9(b) standards require specificity as to the statements (or omissions) considered to be fraudulent, the speaker, when and why the statements were made, and an explanation why they are fraudulent"). This requirement is imposed, at least in part, "to 'alert[] defendants to the precise misconduct with which they are charged and protect[] defendants against

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[8]Notably, this standard does not refer to "pleading" a cause of action for fraud, but merely to "alleging" fraud.

spurious charges of immoral and fraudulent behavior.'" *Pennington v. Vail Prods., Inc.*, No. 303CV1961D, 2004 WL 302298, at *2 (N.D. Tex. Jan. 8, 2004) (Fitzwater, J.) (quoting *United States ex rel. Clausen v. Lab. Corp.*, 290 F.3d 1301, 1310 (11th Cir. 2002)).

In their Complaint, Plaintiffs allege,

> At the time the FDA approved the initial proposed labeling for the Parch, it did not have full knowledge of the dangers inherent in the use of the product, potential defects in the product, or the nature and degree of the risks accompanying its intended use. Similarly, at the time the FDA approved revised labeling proposed by Defendants, it did not have full knowledge of the dangers inherent in the use of the product, potential defects in the product, or the nature and degree of risks accompanying its intended use. The FDA lacked such information because Defendants failed to provide the FDA with existing evidence of product defects and the risks associated with Fentanyl as such evidence was obtained, or should have been obtained. For these reasons, at the time of the incident in question, the FDA had not had an opportunity to assess the current labeling for Fentanyl in light of existing evidence.

Pls.' Compl., Docket No. 1, at 8. Plaintiffs also allege facts about two different recalls of Fentanyl patches because of defects that raised the possibility of a users receiving a potentially fatal dose of Fentanyl. *Id.* at 8-9. The pleadings also contain allegations of the kinds of information that Defendants failed to sufficiently contain in their marketing or reveal in their findings to the FDA, including sufficient testing, provision of sufficient data, the possibility of manufacture with safe materials, and other details. *Id.* at 14-16.

Having considered the impact of *Twombly* and *Iqbal* and the dictates of Rule 9(b), the Court is of the opinion that Plaintiffs, at this stage, have sufficiently pleaded this exception to the presumption in Section 82.007(b). Plaintiffs' pleadings in this case have

sufficiently informed Defendants of the "particulars of time, place, and contents of the false representations." *Williams v. WMX Techs.*, 112 F.3d 175, 179 (5th Cir. 1997). The pleadings demonstrate to Defendants that Plaintiffs are alleging that, in the process of approving the labels for this products, they are alleging that Defendants did not provide the FDA with certain information regarding the risks of overdose from use of the patch, data regarding the patch (of which they provide pleadings regarding testing, monitoring use of the patch, post-marketing surveillance, and other allegations), and the risks inherent in Defendants' design of the patch as opposed to other designs. These allegations are sufficient to provide to Defendants the "who, what, where, when, why, and how" of the alleged fraud. *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997). Defendants know that the allegations involve themselves as those who made the alleged misrepresentations or allegedly withheld the information at issue from the FDA; they know what the information pertained to; they know it was made to the FDA regarding the approval process of the drug at issue; and they know it was done in accordance with regulatory procedures to get their labeling approved by the FDA.

The Court is therefore of the opinion that the pleadings have provided sufficient factual allegations demonstrating to both the Court and Defendants that Plaintiffs may be able to overcome the presumption of Section 82.007(b) and may be entitled to relief. From the pleadings as a whole, the Court has been provided with sufficient factual allegations "to draw the reasonable inference that the defendant is liable for the

misconduct alleged." *Iqbal*, 129 S. Ct. at 1949. Accordingly, the Court shall not dismiss Plaintiffs' claims for marketing defect because their claims have been sufficiently pleaded.[9]

B. Negligent Misrepresentation

To demonstrate negligent misrepresentation, a plaintiff must show that (1) without recognizing reasonable care or competence in communicating information to the plaintiff, (2) the defendant supplied false information to the plaintiff (3) in the course of its business (4) which caused the plaintiff to suffer a pecuniary loss by justifiably relying on the information. *Coburn Supply Co., Inc. v. Kohler Co.*, 342 F.3d 372, 377 (5th Cir. 2007). "The tort [of negligent misrepresentation] involves an intentional statement that was made negligently, or without reasonable care, and that later proves to be false." *Aetna Cas. & Sur. Co. v. Metro. Baptist Church*, 967 F. Supp. 217, 223 (S.D. Tex. 1996) (Hoyt, J.).

Defendants raise the same arguments regarding the heightened pleading standards of Rule 9(b) for their arguments related to pleading fraud on the FDA as supporting their motion to dismiss Plaintiffs' negligent misrepresentation claims. Specifically, they argue that the negligent misrepresentation claim is nothing more than a failure-to-warn claim,

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[9]This, of course, does not foreclose Defendants from asserting on summary judgment or at another later stage that the facts presented to the Court ultimately do not support the allegation that Defendants committed fraud upon the FDA. If Defendants choose to raise that argument at a later stage, the Court will entertain such an argument. At this stage, however, the Court is satisfied that Plaintiffs have demonstrate grounds that they are entitled to relief despite the existence of this presumption.

and is therefore preempted, and that, in any case, Plaintiffs have failed to meet the pleading standards laid out by *Twombly* and Rule 9(b).

As an initial matter, Defendants are incorrect that the heightened pleading requirements of Rule 9(b) apply to Plaintiffs' negligent misrepresentation claims. When the parties do not distinguish between fraud and negligent misrepresentation *claims* in their briefing, then the Rule 9(b) standards apply to both. *Williams*, 112 F.3d at 177. However, Plaintiffs do not raise a *claim* for fraud; rather, they merely allege it to rebut a presumption raised by Defendants as to their marketing defect claims. Therefore, as the negligent misrepresentation claims and the fraud allegations are clearly distinguishable in this situation, "[P]laintiffs' negligent misrepresentation claims are only subject to the liberal pleading requirements of Rule 8(a)." *American Realty Trust, Inc. v. Hamilton Lane Advisors, Inc.*, 115 F. App'x 662, 668, 668 n.30 (5th Cir. 2004).

The Court is of the opinion that Plaintiff's pleadings are sufficient as what Defendants negligently misrepresented. The Complaint provides that "Defendants' misrepresentations include, without limitation, a representation that the Patches would produce a maximum fentanyl blood concentration that was much lower tha[n] the fentanyl concentration found in Decedent's blood at the time of her death and a representation that the Patches were safe for use and a representation that the Patches can be used with other medications." Pls.' Compl., Docket No. 1, at 16-17. These factual allegations, along with others throughout the Complaint, are sufficient to inform Defendants of what information was allegedly improperly conveyed, that the information

was false, that it was provided in the course of business, and that the decedent relied upon the misrepresentation.

As Defendants note, as with Plaintiffs' marketing defect claims, Texas law provides for a presumption of adequate labeling if that labeling was approved by the FDA under Section 82.007(a). Once again, Defendants argue that the fraud-on-the-FDA exception to the presumption is preempted, and that Plaintiffs therefore cannot overcome this presumption. However, as noted above, the Court is of the opinion that the relevant exception is not impliedly preempted by federal law. Furthermore, Plaintiffs have, at this stage, sufficiently pleaded allegations that show that they can overcome this presumption and that they are entitled to relief, and have successfully put Defendants on notice of the alleged fraud at issue. Accordingly, the Court shall not dismiss Plaintiffs' claims for negligent misrepresentation.

C. Strict Liability and Negligence Claims for Design Defect

"A design defect renders a product unreasonably dangerous as designed, taking into consideration the utility of the product and the risk involved in its use." *General Motors Corp. v. Sanchez*, 997 S.W.2d 584, 588 (Tex. 1999). To prove a design defect, Plaintiffs must demonstrate that Defendants "could not have provided a safer alternative design." *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 (Tex. 1998). "[I]f there are no safer alternatives, a product is not unreasonably dangerous as a matter of law." *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995)

Defendant argues that Plaintiff's design defect claims must be dismissed because Texas law, which follows comment k to Section 402A of the RESTATEMENT (SECOND) OF TORTS, provides that prescription drugs are exempt from design defect claims. Comment k provides that certain products are "unavoidably unsafe," and specifically refers to prescription drugs falling within such a category. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). Comment k provides, "The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." *Id.*

Defendants are correct that Texas law follows Section 402A and comment k, *Reyes v. Wyeth Labs.*, 246 F.2d 1264, 1274-75 (5th Cir. 1974); *Croker v. Winthrop Labs.*, 514 S.W.2d 429, 433 (Tex. 1974), and that comment k provides for immunity for design defects in claims made regarding prescription drugs.[10] Several district courts in this circuit have acknowledged that Texas law, following these provisions, does in fact bar design defect claims for prescription drugs. *See Lofton*, 682 F. Supp. 2d at 678-79 (noting that Texas courts have applied comment k to prescription drugs but declining to extend the immunity provided to over-the-counter drugs); *Hackett v. G.D. Searle & Co.*,

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[10]Notably, comment k does not act to bar other types of claims involving the manufacture of prescription drugs, such as manufacturing flaws or defective warnings.

246 F. Supp. 2d 591 (W.D. Tex. 2002) (Sparks, J.).[11] The parties particularly debate the meaning of Judge Sparks's decision in *Hackett*; Defendants claim that *Hackett* stands for the proposition that comment k and Texas law provides that Plaintiffs cannot raise design defect claims for any prescription drugs, while Plaintiffs allege that *Hackett* is limited to Celebrex, the prescription drug at issue in that case. However, in the Court's opinion, neither party has interpreted *Hackett* exactly right. *Hackett* does not provide that "the plaintiff could not state a claim for design defect because the product at issue was a prescription drug." Defs.' Reply, Docket No. 13, at 6. Nor was its holding limited to the specific drug or defendants in that case. Pls.' Resp., Docket No. 11, at 18-19. In relevant part, Judge Sparks wrote,

> Defendants do not present evidence that Celebrex in particular is an unavoidably unsafe drug; rather, they urge this Court to rule that all FDA-approved prescription drugs are unavoidably unsafe as a matter of law. Many courts have held FDA-approved prescription drugs unavoidably unsafe as a matter of law. . . . To allow plaintiffs to sue for defective design of prescription drugs would provide a disincentive to companies to develop new drugs and would allow juries to second-guess the FDA's approval of drugs for marketing. The Court thus holds that under Texas law and comment k of the Restatement, Defendants can only be held strictly liable if the drug was not properly prepared or marketed or accompanied by proper warnings.

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[11]One Texas appellate court recently acknowledged the issue of whether comment k and Texas law bars prescription drug design defect claims, but resolved the appeal on other grounds. *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 769 (Tex. App.–Houston [14 Dist.] 2009). In *Brockert*, the appellate court determined that the plaintiff could not raise a claim for design defect regarding a prescription drug because the plaintiff had failed to identify a safer alternative design. *Id.* at 769-71. Here, Plaintiffs have provided two examples of safer alternative designs. *See* Compl., Docket No. 1, at 7-8. Therefore, the Court shall not dismiss Plaintiffs' claims on the same grounds as in *Brockert*, and must therefore address the issue bypassed by that court.

Hackett, 246 F. Supp. 2d at 595 (internal citations omitted).

The Court is of the opinion that *Hackett* provides that design defect claims in strict liability are barred in regard to prescription drugs, *unless* "the drug was not properly prepared or marketed or accompanied by proper warnings." *Id.* *Hackett* did not interpret Texas law as entirely foreclosing design defect claims in strict liability for prescription drugs; rather, the conditions of improper preparation, marketing, or warning must be present. Judge Lindsay also acknowledged this provision in *Lofton*. 682 F. Supp. 2d at 678-79. This is not to say that prescription drugs at issue are not unavoidably dangerous as a matter of law; on the contrary, the Court acknowledges and agrees with the widespread interpretation that comment k provides that prescription drugs in general are unavoidably dangerous as a matter of law. *See, e.g., Brown v. Superior Ct.*, 751 P.2d 470, 482 (Cal. 1988). However, even in *Brown*, a case heavily relied upon by Defendants, the Supreme Court of California held "that a manufacturer is not *strictly liable* for injuries caused by a prescription drug *so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.*" *Id.* at 482-83 (emphasis added).

Accordingly, the Court holds that, under comment k and Texas law, prescription drugs cannot be subject to design defect claims in strict liability, unless the drug was not properly prepared or marketed or was accompanied by improper warnings. Therefore, so long as Plaintiffs can show that the drug was not properly prepared or marketed, or was

accompanied by improper warnings, then their design defect claim in strict liability regarding a prescription drug may stand.[12]

However, even under this interpretation of Texas law, there is a question as to whether the product at issue should be classified as a "prescription drug." The allegedly defective product was a patch that was placed upon the skin that delivered Fentanyl to the bloodstream. Plaintiffs are alleging that the design of the patch was defective and resulted in excessive amounts of Fentanyl being deposited in Mrs. Friske's blood, causing her death. Plaintiffs allege that the patch was merely a container for the prescription drug, and that comment k's provisions do not apply to such a device. In support of this argument, Plaintiffs have alleged that there were two alternative safer designs that Defendants could have used. Defendants, however, argue that comment k's provision of immunity for design defects in prescription drugs (with the caveats determined by the Court above) covers the entire patch at issue, and that Plaintiffs therefore cannot obtain relief for defective design as to the patch, even if there were safer alternatives to the design used by Defendants. Thus, the Court is faced with the question of whether Texas

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[11]Notably, Plaintiffs' pleadings include an allegation that a number of patches manufactured by Defendants that contained expiration dates of December 2009 were recalled in February 2008 "because a cut alongside of the drug reservoir within the patch resulted in the possibility of a fatal overdose." Compl., Docket No. 1, at 9. While Plaintiff does not allege that the patch at issue was among those that should have been recalled, this allegation does raise questions as to whether one of the exceptions to immunity for design defect as noted in the aforementioned cases, such as proper preparation of the product or improper warning, is present.

law's provision of immunity from design defect claims for manufacturers of prescription drugs includes the patch itself, which acted as a delivery mechanism for the drug.

The Court finds guidance from Judge Kimball's decision in *Lake-Allen v. Johnson & Johnson, L.P.*, No. 2:08CV00930DAK, 2009 WL 2252198 (D. Utah July 27, 2009), which regarded similar facts and arguments. In *Lake-Allen*, the wife of a decedent sued the manufacturer of a pain relief patch that delivered Fentanyl, alleging that her husband had died from an overdose of Fentanyl precipitated by the delivery of a deadly amount of the drug due to a faulty "reservoir" system in the patch. *Id.* at *1. Much like Plaintiffs in this case, the plaintiff in *Lake-Allen* alleged that there was a safer alternative "matrix" design. *Id.* The defendant manufacturer moved to dismiss all of the plaintiff's design defect-based claims, which included strict liability and negligence claims, arguing that Utah law, which has also adopted comment k, barred the design defect claims. *Id.* at *2. The plaintiff in *Lake-Allen*, much like Plaintiffs here, asserted that the patch would be more akin to a "container" rather than a prescription drug and therefore not subject to any restriction on design defect claims. *Id.*

Judge Kimball rejected the plaintiff's contention that the Fentanyl patch would be more appropriately identified as a contained rather than a prescription drug. Citing *Grundberg v. Upjohn*, 813 P.2d 89 (Utah 1991), which held that comment k barred strict liability claims for defective design of prescription drugs, Judge Kimball wrote,

> The [Fentanyl] patch was approved by the FDA as a drug and to categorize it as a container is akin to categorizing any substance available in a time release capsule as a container. In the case of prescription pharmaceutical

> patches, it is nonsensical to separate the liability of the overall product and the substance that it releases. As such, *Grundberg* applies and Plaintiffs' strict liability claim is dismissed to the extent that it is based on a theory of design defect.

Lake-Allen, 2009 WL 2252198 at *3; *see also Grange, Jr. v. Mylan Labs., Inc.*, No. 1:07-CV-107 TC, 2008 WL 4813311, at *5 (D. Utah Oct. 31, 2008) (dismissing a plaintiff's strict liability claims for design defect of a Fentanyl pain relief patch).

The Court agrees with Judge Kimball's reasoning, and determines that "prescription drug" includes the entire product, not just the medication.[13] Therefore, because the Patch is a prescription drug, comment k, as adopted by Texas law, applies to Plaintiff's claims regarding the defects in the design of the patch. However, there are two reasons why Plaintiffs' design defect claims should not be dismissed at this stage. First, comment k, by its own terms, is limited to claims in strict liability; as Judge Sparks noted, "Defendants can only be held *strictly liable* if the drug was not properly prepared or marketed or accompanied by proper warnings." *Hackett*, 246 F. Supp. 2d at 595 (emphasis added). Judge Kimball also noted this distinction, holding that the immunity

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[13]As Defendants point out, this position is supported by the Supreme Court's decision in *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983). In *Generix*, the Supreme Court was faced with the question of whether the term "drug" in certain provisions in the Federal Food, Drug, and Cosmetic Act "refers only to the active ingredient in a drug product or to the entire product." *Id.* at 454. The Supreme Court held "that Congress intended the word to have the broader meaning," noting that "[t]he active ingredients in most prescription drugs constitute less than 10% of the product; inactive 'excipients' (such as coatings, binders, and capsules) constitute the rest." *Id.* While this case dealt with federal rather than Texas law, the Court is of the opinion that the Supreme Court's reasoning supports the determination by this Court and Judge Kimball that a "prescription drug" includes the entire product, including its delivery mechanism.

provided by comment k applies only to design defect claims based in strict liability and accordingly limiting the dismissal of the plaintiff's design defect claims to those based in strict liability, allowing the negligence claims to proceed. *Lake-Allen*, 2009 WL 2252198 at *3. The Court agrees with the approaches of Judges Sparks and Kimball, and shall not apply comment k to design defect claims that are not based in strict liability.[14]

Second, comment k provides for immunity from liability for claims based in strict liability for prescription drugs, but that immunity is limited to where "the drug was not properly prepared or marketed or accompanied by proper warnings." *Hackett*, 246 F. Supp. 2d at 595; *see also Keene Corp. v. Rogers*, 863 S.W.2d 168, 176 (Tex. App.–Texarkana 1993, no writ) ("[T]he manufacture and sale of unavoidably unsafe products is reasonably despite the risk, *so long as the manufacturer or seller properly warns consumers*.") (emphasis added). In this case, Plaintiffs have alleged that the product at issue was subject to improper marketing, manufacturing defect, and the failure to provide adequate warnings. Such allegations, if proven, would, satisfy these recognized exceptions to immunity for claims in strict liability for design defect in prescription drugs. Considering the fact that Plaintiffs' pleadings do allege such actions

[14]Defendants urge the Court not to differentiate between negligence and strict liability claims in regard to the barring of design defect claims under comment k, referring the Court to the Georgia Supreme Court's decision in *Jones v. NordicTrack, Inc.*, 550 S.E.2d 101, 103 n.5 (Ga. 1999). However, the Court is convinced that comment k is by its own terms limited to strict liability claims, as recognized by Judges Sparks and Kimball in *Hackett* and *Lake-Allen*, respectively. If the drafters of comment k had intended for the immunity provided to apply to claims beyond those in strict liability, the Court is of the opinion that they would have specifically mentioned these immunities as applying to claims beyond strict liability, rather than specifically identifying strict liability claims, in comment k.

by Defendants, the Court is convinced that these exceptions have been properly pled and that dismissal of these claims at this stage would be inappropriate. The Court shall therefore deny Defendants' Motion to Dismiss as to Plaintiffs' design defect claims.[15]

D. Breach of Implied Warranty of Fitness

At the hearing, Plaintiffs informed the Court that they were not challenging Defendants' Motion to Dismiss as to their implied warranty of fitness claims. Accordingly, the Court shall grant Defendants' Motion as to this claim.

IV. Motion for Leave to Amend

In their Motion, Plaintiffs ask the Court, in the alternative of denying Defendants' Motion, to grant them leave to amend their pleadings. Defendants oppose the request, arguing that the Motion was brought improperly under the Local Rules and that any amendment would be futile. However, as recounted above, the Court is of the opinion

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[15]Defendants also note that Texas law includes a presumption that a manufacturer is not liable in a products liability action for a design defect if the product at issue was subject to licensing or approval by the federal government or a federal agency, that the manufacturer complied with all of the relevant federal procedures and requirements for such licensing or approval, and that the product was approved after full consideration of the product's risks and benefits. TEX. CIV. PRAC. & REM. CODE § 82.008(c). This presumption can be rebutted by a showing similar to the "fraud-on-the-FDA" provision discussed above that related to Plaintiffs' marketing defect claims. TEX. CIV. PRAC. & REM. CODE § 82.008(c)(2). However, Section 82.008(e) provides that "[t]his section does not extend to products covered by Section 82.007," which includes "pharmaceutical products" like the one at issue here. However, Section 82.007 concerns warnings and labeling, not design, and the parties have not addressed whether this provision in Section 82.008 applies to the patch at issue in this case. In any case, because the Court is convinced that Plaintiffs have sufficiently pled their claims for fraud on the FDA at this stage, the Court shall not dismiss Plaintiffs' claims on this ground, but will address the issue at the summary judgment stage should Defendants choose to raise such an argument.

that Plaintiffs have sufficiently pleaded their claims for marketing defect, negligent misrepresentation, and design defect, and the have dropped their claim for breach of implied warranty of fitness. Because the Court is convinced that Plaintiffs' pleadings are sufficient as to these first three claims, amendment to the pleadings is not necessary to overcome any deficiencies. However, because one of Plaintiff's claims will be dismissed, the Court shall allow Plaintiffs leave to amend to allow them the opportunity to streamline their claims and provide a live pleading that contains all of Plaintiffs' remaining pending claims. The Court is of the opinion that, at this early stage in litigation, such an action would not prejudice Defendants and is well within the Court's discretion to permit leave to amend "when justice so requires." *See United States ex rel Adrian v. Regents of the Univ. of Cal.*, 363 F.3d 398, 403 (5th Cir. 2004); FED. R. CIV. P. 15(a)(2).

Conclusion

For the reasons stated above, Defendants' Motion for Partial Dismissal is GRANTED IN PART AND DENIED IN PART. As to Plaintiffs' claim for breach of implied warranty of fitness, Defendant's Motion to Dismiss is GRANTED, and that claim is accordingly DISMISSED WITHOUT PREJUDICE. As to Plaintiffs' claims for marketing defect, negligent misrepresentation, and design defect in strict liability and negligence, Defendants' Motion to Dismiss is DENIED.

Furthermore, Plaintiffs' Motion for Leave to Amend is GRANTED. Plaintiffs are granted leave to file an Amended Complaint within **21 days** of this Order containing their remaining claims.

IT IS SO ORDERED.

SIGNED this 29th day of April, 2011.

Royal Furgeson
Senior United States District Judge